AMENDMENTS TO THE DRAWINGS

The attached "Replacement Sheets" of drawings include changes to Figures 3 and 4. The attached "Replacement Sheets," which include Figures 3 and 4, replace the original sheets including Figures 3 and 4.

Attachment: Replacement Sheets

REMARKS

In this response, claims 1, 2, 4, 5, 31, 33, 45, 59, 72-74, 85, and 100-129 have been amended. Original claim 90 is followed by incorrectly numbered claim 100. Accordingly, original claim 100 and subsequent claims have been renumbered 91 onwards. As a result, upon entry of the amendments claims 1-120 remain pending, even though no claims have been cancelled.

Claim 2 has been amended to change the transitional phrase "consists essentially of" to "comprises".

Original claim 124 has been amended to correct a typographical error.

Support for the claim amendments

Support for the amendments is found in the specification. For example, support for the limitation that the tablet "achiev[es] said extended release of said metformin by the design of the coating" can be found on the first line of paragraph [0025], which states the "coating is designed to achieve an extended release of said metformin". This applies to claims 1, 31, 59, 85, 110, 114, 116, and 117.

The limitation that the core is an "immediate release" core is evident from this sentence and is also inherent in the examples. This applies to claims 1, 31, 59, and 85. When discussing new matter and the written description requirement, MPEP 2163 (1)(B) paragraph 2 states:

> "While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."

Thus, literal or express support is not required, but the claimed subject matter must be implicit or inherent in the disclosure. The sufficiency of the disclosure is assessed in light of the understanding a person of skill in the art would have upon reading it. The requirement is often stated in permissive form: it is sufficient that the specification convey clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed.

In this light, Applicants point out that the disclosure, after describing the cores in paragraph [0024], follows at paragraph [0025] stating "These tablet cores are then coated with a coating designed to achieve an extended release of metformin". This necessarily means that the cores containing metformin are not designed to achieve an extended release, since the description teaches such a release is to be achieved with the design of the coating. In other words, the instant release nature of the cores is implicit from the description at paragraph [0025], in context. The immediate release nature of the cores is also clear from the Examples such as 1A, 1B, and 3A. From considering the core formulations of the Examples, the person of skill in the art would understand that the cores are inherently immediate release cores. Because the limitation is implied in the description and inherent in it, Applicants submit the amended claims comply with the written description requirement.

Support for claims that recite a pharmaceutically acceptable salt of metformin is found in the specification for example at paragraph [0021]. Support for claims that recite metformin hydrochloride is found in the specification for example at paragraph [0008].

No new matter is added. Applicants respectfully request entry of the amendments.

Objection to the Specification

The specification is objected to as failing to provide proper antecedent basis for subject matter claimed in claims 128 and 129. Applicants have amended the specification by introducing the subject matter of claims 128 and 129 (as filed) at paragraphs [0015A] and [0015B]. No new matter is added. Applicants respectfully request the objection be withdrawn.

Objection to the Drawings

Original Figures 3 and 4 have been objected to because of the typographical error in the word "dissolved" which appears as "diss lved". Pursuant to 37 CFR 1.121(d), Applicants attach herewith Replacement Sheets for Figure 3 and 4 correcting this typographical error. Applicants request the objection be withdrawn.

REJECTION UNDER 35 U.S.C. §112

Original claim 2 has been rejected under 35 U.S.C. Section § 112, paragraph 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention because of the use of the transitional phrase "consists essentially of". The Office considers the use of "consists essentially of" as indefinite because "it is not clearly defined in the specification." Applicants respectfully disagree. Nevertheless, in an effort to advance prosecution, Applicants have amended claim 2 to recite the transitional phrase "comprising." Accordingly, Applicants submit that this rejection is now rendered moot and request withdrawal of this rejection.

REJECTION UNDER 35 U.S.C. §102

1. Moeckel *et al.* (US Patent 5,955,106)

Claims 1, 2, 6-18, 20, 22, 29 and 30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Moeckel *et al.* Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

Moeckel does not teach or suggest the immediate release cores of the amended claims, and does not provide a coating "achieving ... extended release of ... metformin," as recited in those claims. Rather, Moeckel is drawn to delayed or extended release cores.

The Moeckel Abstract itself states the compositions contain metformin and "a hydrocolloid-forming agent as a retardant," where it is clear from the rest of the disclosure that the retardant makes the cores have an extended release. Further, in column 3, lines 53-60, Moeckel teaches:

> "The compressed forms of administration that are produced using the pharmaceutical composition according to the invention such as for example metformin delayed-release tablet cores can be additionally provided with a film envelope. The film envelope can on the one hand cause an additional retardation by using those film materials which represent a film-forming agent which is usually suitable for these purposes." *Emphasis added.*

The passage clarifies the cores are extended release. The disclosure of Moeckel does not teach or suggest the immediate release cores of the amended claims.

Further, the Moeckel disclosure does not teach a coating that is permeable to metformin, as recited in the claims. The limited teaching of film envelopes in Moeckel does not provide an operable technique to produce a coating that is permeable to metformin. For this additional reason, the Moeckel reference does not anticipate the claims.

Applicants respectfully submit the amended claims are patentable over the reference, and request the rejection be withdrawn.

2. Cheng *et al.* (US Patent 6,099,859)

Claims 1, 2, 7-13, 15, 17-19, 22, 29 and 30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Cheng *et al.* Applicants traverse the rejection and request reconsideration.

The Cheng reference discloses a coating impermeable to metformin. At column 4, lines 10-17, it states:

> "The homogenous core is coated with a semipermeable membrane, preferably a modified polymeric membrane to form the controlled release tablet of the invention. The semipermeable membrane is permeable to the passage of an external fluid, such as water and biological fluids and is impermeable to the passage of the anti-hyperglycemic drug in the core." *Emphasis added.*

The reference does not disclose or suggest the permeable coating of the amended claims. Applicants respectfully submit the claims are patentable over the Cheng reference and respectfully request the rejection be withdrawn.

3. Seth (US 6,350,471B1)

Claims 1-4, 6-14, 16-22, 28-32, 34-42, 44-50 and 56-58 stand rejected under 35 U.S.C. 102(e) as being anticipated by Seth. This rejection is respectfully traversed.

Contrary to the position taken in the Office Action, the Seth reference does not disclose every limitation of the amended claims. In particular it does not disclose a core comprising metformin. Throughout, the cores are said to contain oxybutynin hydrochloride, propranolol hydrochloride, buspiron hydrochloride, niacin, cetirizin hydrochloride, cerivastin sodium, metoprolol fumarate, and alendronate sodium. *See* BACKGROUND; *see also* col. 1, lines 61-65. The reference does not teach or suggest a core containing metformin. The reference to metformin in column 2 (at lines 26-28), stating the cores are coated with a coating designed to achieve a controlled release of metformin, is not by itself a teaching that the cores contain metformin. In context, as understood by a person of skill in the art, the reference to metformin is unexplained. There is no other mention of metformin. In fact, as noted, the specification teaches the cores do not contain metformin.

Because the reference does not disclose every limitation of the amended claims, Applicants respectfully request the rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §103

For a rejection under 35 U.S.C. § 103 over a combination of references to be sustained, the references must teach or suggest every limitation of the claims. If any element or limitation of the claims is missing from the combined references, rejection is improper and should be withdrawn.

1. Moeckel *et al.* (US Patent no. 5,955,106) in view of Buhler *et al.* (US Patent No. 6,592,900B1) and/or Remington's Pharmaceutical Sciences 1990 18th Ed. Chpt. 89, p1637.

The claims are rejected as being unpatentable over Moeckel in view of Buhler *et al.* and/or Remington. This rejection is respectfully traversed.

The rejected claims recite immediate release cores. Claims 1, 31, 59, and 85 have been amended to recite this requirement explicitly, while claims 110, 114, 116, 117, 118, 119, and 120 recite cores that are inherently instant release, based on their compositions.

In contrast, the Moeckel reference is drawn to tablets that contain delayed release cores, as explained above. Applicants respectfully submit the secondary references do not overcome those deficiencies of the Moeckel reference. The combined references do not disclose every limitation of the rejected claims. Accordingly, Applicants respectfully request the rejection be withdrawn.

2. Cheng *et al.* (US Patent 6,099,859) in view of Buhler *et al.* (US Patent No. 6,592,900B1) and/or Remington's Pharmaceutical Sciences 1990 18th Ed. Chpt. 89, p1637.

The claims are rejected as being unpatentable over Cheng in view of Buhler *et al.* and/or Remington. This rejection is respectfully traversed.

The Cheng reference discloses tablets with coatings that are impermeable to metformin, while all of the rejected claims recite that the coating is permeable. The secondary references do not overcome those deficiencies of the Cheng reference, which are also discussed above. That is, the references even when combined do not disclose each and every limitation of the rejected claims. Accordingly, Applicants respectfully request the rejection be withdrawn.

3. Seth (US 6,350,471B1) in view of Buhler *et al.* (US Patent No. 6,592,900B1) and/or Remington's Pharmaceutical Sciences 1990 18th Ed. Chpt. 89, p1637.

The claims are rejected as being unpatentable over Seth in view of Buhler *et al.* and/or Remington. This rejection is respectfully traversed.

The secondary references do not overcome the deficiencies of the Seth reference, discussed above. Thus, the combined references do not disclose every limitation of the rejected claims. Accordingly, Applicants respectfully request the rejection be withdrawn.

CONCLUSION

For the reasons discussed above, Applicants believe that claims 1-120 are in an allowable state and respectfully request an early notice of allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

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